STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY

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Date: November 26, 2002

To: The Record

From: Emergency Response Unit

Subject:

We are pleased to provide the following report on this investigation undertaken by our Unit.

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Investigator #61, Emergency Response Unit

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Final Report – 10/29/02

E. coli O157:H7 Illnesses in Washington – July, 2002

Background Information

On July 29, 2002, U.S. Food and Drug Administration (FDA) notified California Department of Health Services Food and Drug Branch (FDB) of a cluster of illnesses due to E. coli O157:H7 in Washington State. Initial cases were reported from 130 participants attending a drill team/dance camp at Eastern Washington University (EWU) in Cheney, Washington, from July 11-15, 2002. As of August 3, 2002, Washington Department of Health (WDH) staff identified 40 cases of lab-confirmed illness with E. coli O157:H7. Approximately 6 of these cases were hospitalized, 1 with complications from Hemolytic Uremic Syndrome (HUS). Onset dates initially reported for lab confirmed cases ranged from July 12-18, 2002 with a peak on July 14,2002 (Attachment 1). Isolates with indistinguishable PFGE patterns were reported for 14 of these cases, with additional PFGE's pending.

A cohort study of 102 campers conducted by Spokane Regional Health Department revealed a statistically significant association with consumption of romaine lettuce (98% vs. 52%, RR=15.97, $p<0.0001$) and with consuming water from coolers on the athletic field. The Center for Disease Control (CDC) and Center for Food Safety and Applied Nutrition (CFSAN) concurred with the conclusion that salad was the likely primary vehicle and water was the secondary vehicle due to bare hand contact with ice in water coolers.

In addition, WDH investigators reported 4 cases in another area of eastern WA, one case in Idaho, and one case in Minnesota with a PFGE pattern indistinguishable from the "outbreak" pattern. These cases each had onsets of illness during the same time period. However, none of these cases attended the cheerleading camp or had contact with individuals attending the camp.

WDH investigators reported no pre-existing illnesses among foodworkers at the cheerleading camp and the workers wore gloves at all times when handling the romaine lettuce. Other ingredients in the romaine salad consisted of croutons, Parmesan cheese, and a commercial dressing.

Romaine lettuce supplied to the cheerleading camp was packaged by Spokane Produce in 5-lb bags and labeled as "Processed Pre-Cut Vegetables".

Traceback Investigation

On Friday, August 2, 2002, FDA-Seattle District Compliance staff and FDA-Emergency Operations staff provided specific information on suppliers of romaine lettuce implicated in a cluster of illnesses due to E. coli O157:H7 in July of this year. Three California firms were identified by FDA-Seattle District and Emergency Operations staff for further investigation (Capurro Farms, Mann Packing, and Ocean Mist Farms). FDA-Alameda staff and FDB staff made arrangements to begin the investigation in California on Friday, August 2, 2002.

Investigator Jim Sigl and Dr. Jeff Farrar met FDA investigators Bill Weiss and Carl Lee near Salinas Friday afternoon (August 2, 2002) to begin the investigation. Investigator Sigl teamed

with Bill Weiss to visit Capurro Farms in Moss Landing. Dr. Farrar and Carl Lee visited Ocean Mist Farms in Castroville.

In a subsequent conference call, FDA staff relayed that product supplied by Ocean Mist Farms was not likely present at the time of the implicated meal at the dance team/drill team camp in Washington and therefore should not be included in the traceback assignment. The Ocean Mist investigation is included in this report because it was completed after the initial traceback request by FDA. During this subsequent call, FDA relayed information that another firm, River Ranch, was also a possible supplier of romaine lettuce associated with cases who did not attend the drill team camp.

Environmental Investigation of Ocean Mist Cooling/Shipping Facility

Upon arrival at the Ocean Mist Farms office in Castroville, investigative staff was introduced to Mr. Joe Pezinni, Vice President of Operations for Ocean Mist Farms cooling and shipping facility in Castroville. Following a brief explanation of the reason for the visit, Mr. Pezinni stated that he was aware of the issue and had completed some initial records review. During our investigation at this facility, we also met and received information from Mr. Joe DeSante (Manager of Facilties and Supplies) and Mr. Dave Bernardasci (Manager of Cooling and Receiving).

Mr. Pezinni provided an explanation of the practices and procedures at the Ocean Mist Farms cooling and packing facility during a walk-through. The general flow of events consists of 1) receiving 2) data entry/pallet tagging 3) cooling 4) quality assessment and 5) shipping. After a physical review of the entire process, the most likely opportunity for unintentional contamination at this facility was determined to be point 3. Therefore, additional examination of this point was completed.

Ocean Mist Cooling

Cooling of romaine lettuce at this facility occurs by creating a negative pressure inside a sealed piece of equipment, frequently referred to as a " vacuum tube" (even though some are not cylindrical) or "hydrovac's". "Wet" or "dry" hydrovac treatments are applied depending upon the product and type of packaging. Wet treatment involves an application of water during the cooling cycle. Dry treatment does not receive an application of water although water may be present in the reservoir of the tube.

Heads of romaine lettuce in waxed cardboard boxes with no plastic liner or wrapping (called Naked lettuce) received a wet cooling process. Romaine in cardboard cases with plastic liners or individual romaine heads wrapped in plastic receives a dry cooling process. For both processes, the goal is to rapidly cool the product to approximately 34 degrees Fahrenheit to preserve the shelf life. Temperatures of product entering the vacuum tube and exiting the vacuum tube are recorded (Attachment 2 and Attachment 4B).

Specifically, the wet hydrovac process involves loading several hundred cases of product into the vacuum "tube". The "tube" resembles a railroad car with large doors at both ends to allow entrance and exit of product loads (Attachment 3). The doors are sealed and a vacuum is created, beginning the cooling process. As the atmospheric pressure decreases within the "tube", the rate of evaporation (and thus cooling) increases. At some point or points during the wet hydrovac process (varies by firm), water is pumped from a reservoir in the bottom of the tube to the top of the tube and applied through nozzles to the product (Attachment 4C.). This water circulates down through the hundreds of cases of product during the cooling cycle. The water is

reportedly added to replenish moisture lost during the vacuum cooling process. Water may be added throughout the day to the reservoir to replenish losses during the cooling cycles. The time required for reaching 34 degrees Fahrenheit is dependent upon the incoming temperature and density of the product, the number of cases being cooled, and the efficiency of the mechanical equipment. Internal temperatures of the tube and atmospheric pressure are monitored during the cooling process. For these shipments, the approximate cooling time was around 1 hour from entry into to the hydrovacuum to exit.

Dry vacuum treatment is essentially the same process as described above without the direct application of water. However, in some cases, there may be water present in the reservoir of the vacuum tube, which may result in some vaporization during the negative pressure cooling cycle.

Ocean Mist staff has standard operating procedures (SOP's) for decreasing the likelihood of cross contamination by water used in the wet vacuum (hydrovacuum) cooling process (Attachment 5). The SOP calls for a minimum Oxidation-Reduction Potential (ORP) level of 650 mV prior to each cooling cycle (an ORP reading is not done on the initial cycle each day) to prevent cross contamination of product from water used for previous cooling cycles. Prior to each wet vacuum cooling cycle, Ocean Mist Farms staff monitor and record the ORP of the water (Attachment 6). If the ORP is less than 650 mV, liquid chlorine (6.5% food grade sodium hypochlorite) is added until the ORP level meets or exceeds the target (Attachments 4D). The equipment used to monitor the ORP level was an Ultrameter serial number 300678 manufactured by Myron L Company, Carlsbad, California. Ocean Mist Farms staff provided copies of calibration logs of this ORP measuring device (Attachment 7). At the end of each day (and as needed during the day), the water is drained from each of the vacuum tubes and a pressure wash is completed. The water reservoirs are filled in the mornings before the first wet cooling cycle.

Following the end of the cooling cycle, the temperature of the product is recorded and the pallets are moved by forklift from the tube to the refrigerated storage area (ambient temperature 34 degrees Fahrenheit). Here, product is held from a few hours to several days. Product is color coded upon arrival at the facility (through pallet tags) to indicate what day it arrived. Product is loaded according to a First In-First Out procedure utilizing this color-coding scheme. Ocean Mist Farms staff reported that product generally is shipped within 1-2 days of receipt and that the maximum time product remains in Ocean Mist's cooling facility would be 7-8 days.

Ocean Mist Cooling

Farm Investigation

Mr. Pezzini was able to quickly identify two farms (three fields) as having supplied the romaine shipped to Spokane Produce from Ocean Mist Farms. Ranch identification numbers on the customer order records identified these farms (Attachment 8). The farms included Boggiatto Ranch – Fields 3A and 4B (codes 21QB1N and 2IQB1M) and Mortensen Ranch – Field 9 South (code 2IQDIE). Ocean Mist provided invoices showing the shipment of 140 cases on June 27, 2002 to Spokane Produce.

Mr. Pezzini accompanied FDB and FDA investigators to each of these fields. Single longitude and latitude measurements were recorded for each field using a Garmin GPS-12 device and are presented on the maps (Attachment 9) and in the traceback diagram (Attachment 10).

Mortensen Ranch – Field 9 South

Mortensen Ranch, field 9 South (approximately 11 acres) was surrounded by other crop production fields. However, this particular field (9 South) was no longer in lettuce production. Ground preparation activities were in progress to prepare for a second planting (a non-lettuce crop). Mr. Pezzini stated that no manure had been used on this (or any of his Ocean Mist fields) for at least three years. Water used for irrigating Field 9 South is from a deep water well on the south side of the field. The wellheads appeared to be properly sealed. FDA Investigator Carl Lee collected a water sample from this well for further analysis (coliform, E. coli) (Attachment 11).

Harvesting of this field was performed by Valley Pride, a harvesting contractor affiliated with Ocean Mist Farms. Portable toilet facilities are reportedly provided for employees during harvesting.

Boggiatto Ranch – Fields 3A and 4B

These fields (each approximately 5 acres) were surrounded by other crop production fields. Both fields were no longer in lettuce production. Ground preparation activities were in progress to prepare for a second planting (a non-lettuce crop). Mr. Pezzini stated that no manure had been used on this field for several years. Water used for irrigating these fields is tertiary treated wastewater from the Monterey Regional Water Pollution Control Agency (Attachment 12). FDA Investigator Carl Lee collected a water sample from an outlet that provides tertiary treated water to these fields (Attachment 11).

Harvesting of this field was performed by Valley Pride, a harvesting contractor affiliated with Ocean Mist Farms. Specific individuals participating in the harvesting of this field were identified from time cards at Valley Pride and are summarized in Attachment 13. Portable toilet facilities are reportedly provided for employees during harvesting. Investigators observed a portable toilet used by workers harvesting an adjacent field.

Traceforward Information

Ocean Mist Farms staff provided FDB and FDA with an electronic spreadsheet file of all customers receiving product from each of the three fields. Dr. Farrar reviewed this data and determined that there was a very wide geographic distribution of product from each of these fields. Due to the confidentiality of customer information, the Ocean Mist spreadsheet will not be included in this report.

Environmental Investigation of Frank Capurro and Sons

FDA Investigators Bill Weiss and Erica Pomeroy and FDB Investigator Jim Sigl met Mr. John Manfre, Partner of Frank Capurro and Sons and Mr. James De Lorimier, Salesperson for Frank Capurro and Sons at the office of Frank Capurro and Sons in Watsonville on August 2, 2002. After learning of the purpose of the visit, Mr. Manfre provided information and copies of requested documentation. The firm identified three shipments of romaine sent to Spokane Produce between June 26, 2002 and July 10, 2002 (Attachment 14). These shipments were grown by Dobler and Sons, Watsonville, California. These shipments were from four fields on three ranches near Watsonville, California. The ranches were identified as Struve, Balich and Hudson. The plots from these ranches were Struve 3A, Balich 4A and 5B, and Hudson 1A.

Mr. Manfre informed investigators that all three of the shipments sent to Spokane Produce were placed in 24 pack boxes in the field then sent to Unikool, Salinas, California for cooling and storage prior to shipment. Attachment 15 shows the traceback diagram for romaine harvested from the Dobler and Sons fields to Spokane Produce. Field heat is removed from the liner pack product by vacuum cooling with no water shower and then the product is placed in cold storage until shipment. The product designated "naked" is placed directly in a waxed cardboard box and then is sent to Unikool where it is placed in a hydrovacuum tube and then moved into the cold storage facility pending shipment.

Dobler and Sons, LLC.

Farm Investigation

Mr. Matt Conley, Harvest Manager for Dobler and Sons met with FDB and FDA investigators at the identified fields. Water samples were collected from each of 3 wells supplying water to the four fields (Attachment 16). Mr. Conley informed us that the firm does not use manure or fertilizers from outside sources, they use crop rotation and green fertilizers. Green fertilizers are crops that are not harvested, but plowed into the ground as a soil amendment. During this inspection, the harvesting crew had finished for the day and therefore, we did not have a chance to observe one of the firm's harvesting crews. All harvesting is done by Dobler and Sons' harvest crews. We did arrive at a ranch run by Dobler and Sons as the harvest equipment was being packed. A portable restroom trailer was present in the field. This trailer had three portable stalls on board (Ajax Portable Services), single service towels, soap, and water were provided. The trailer had a built-in catch basin for the hand-washing water to fall into.

The Balich plots (4A and 5B) observed were located approximately ½ mile west of San Miguel Canyon Road and immediately south of the railroad tracks. The wellhead appeared to have an intact concrete seal. FDA investigators took a water sample from an irrigation spout located in field 4A. The sample was negative for E. coli (Attachment 16).

The Hudson 1A plot was located about one mile west of Salinas Road, just south of Trafton Road. The plot was surrounded by other farmland. FDA investigators took a water sample from a field irrigation outlet in field 1A. The sample was negative for *E. coli* (Attachment 16).

The Struve 3A plot is located approximately 1 mile west of Highway 1, just northwest of West Beach Street. The surrounding area is flat farmland. Approximately ½ mile away, south of West Beach Street, is the Watsonville wastewater treatment plant. FDA investigators took a water sample at the well. The sample was negative for *E. coli* (Attachment 16).

Unikool Cooling

Dobler and Sons transported the field-packed lettuce to Unikool, 730 West Market Street, Salinas, California for cooling and cold storage immediately after harvesting.

Investigator Jim Sigl, Dr. Jeff Farrar, Mr. Bill Weiss, and Mr. Lee met at Unikool with Mr. Ron Herman, Manager, Unikool and Mr. Greg Smith, Supervisor, Unikool. Mr. Smith said that Mr. Bart Bonfantini, Plant Manager, Unikool had left for the day and he would be the best person to provide records. Mr. Herman stated that the firm uses three hydrovacs. He said that the water is chlorinated and analyzed for chlorine content every fourth or fifth load. One hydrovac had its doors open and the investigative team was able to look inside the tube. It was noted that the

hydrovac was empty at the time of inspection. Mr. Herman said that each regular hydrovac could cool 24 pallets per load.

Investigator Carol Myers met FDA investigators Bill Weiss and Erica Pomeroy in Salinas Thursday morning (August 8, 2002) and visited Unikool and Costa and Sons Farms.

Mr. Bart Bonfantini, Plant Manager for Unikool, 730 W. Market St., Salinas, California met with FDB and FDA investigators. Documentation was provided that showed the receipt and cooling of the implicated romaine from Capurro and Son (Attachment 17).

Unikool uses forced air, hydrovacuum, and vacuum cooling methods to remove field heat from product. Unikool has five hydrovacuum tubes; one of these tubes is used strictly as a vacuum tube and never has water in the reservoir (Attachment 4A). The other tubes are used to cool product either wet or dry. Mr. Bonfantini said that they cool (wet and dry) approximately 50,000 cases a day.

Three shipments of the implicated romaine lettuce from Frank Capurro and Son were shipped to Unikool before being shipped to Spokane Produce (Attachment 17). Of these shipments, two were boxed in liner packs. Mr. Bonfantini said the liner packs from Capurro and Son were dry vacuum cooled in a hydrovacuum tube that had water in the reservoir. Water was not showered over this product. Mr. Bonfantini said that during this process there was no misting from the reservoir water, the load was not introduced to reservoir water, and remained dry throughout the cooling cycle. Romaine lettuce is cooled for approximately 30 minutes.

One load received at Unikool from Capurro and Son was hydrovacuum cooled. This shipment was received as a "naked" load. Water was recirculated from the reservoir to the showerheads and rained over the product.

Operators fill out an "Equipment Cleaning Checklist" documenting the start-up procedures for the hydrovacuum tubes (Attachment 18). The tubes are cleaned and fresh water and chlorine (liquid, 12% sodium hypochlorite) are added before the day's first cooling load. Mr. Bonfanitini told investigators that 64 ounces of food grade chlorine is added once (in the morning) to the hydrovacuum tubes regardless of how many loads are cooled throughout the day. This is the only chlorine addition to the tube for the day.

The Oxidation-Reduction Potential (ORP) of the reservoir water in tube 105HV taken by Investigator Myers was 532mV. An OAKTRON ORP Testr Double Junction meter was used to take this measurement. The drum of liquid chlorine (12% sodium hypochlorite) used to sanitize the hydrovacuum tube reservoir water was empty on August 8, 2002. Mr. Bonfantini said that Unikool was using chlorine from Mills Distributing, a neighboring firm until they purchase more chlorine. FDA investigators collected a water sample from Hydrovacuum 105HV which tested negative for *E. coli* 0157:H7 (Attachment 19). Daily records are not kept documenting the level of chlorine or ORP level in the recirculating water of the hydrovacuum tubes. After cooling, product is transferred to a cold storage room where it remains until the customer arranges the sale and transport of the product.

Environmental Investigation of Mann Packing Co.

Investigator Jim Sigl, Bill Weiss, and Erica Pomeroy visited Mann Packing Company on August 5, 2002. Mr. Tom Mangino, VP of Operations, Mann Packing Co. and Ms. Esther Hofmeister, Manager of Food Safety, Mann Packing Co. represented the firm and supplied requested

documentation. Ms. Hofmeister informed investigators that they had sent one shipment of romaine to Spokane Produce between June 26, 2002 and July 11, 2002. The firm provided invoices, which showed that they shipped 105 cases of Romaine to Spokane Produce on July 6, 2002 (Attachment 20). These cases were 24-count liner-pack romaine under the "Sunny Shore" label. The romaine was received from the grower, Costa and Sons on July 5, 2002. Mr. Mangino informed us that this product is placed in liner boxes in the field then transported to Mann Packing Company where it was vacuum cooled and cold-stored until shipment.

The firm informed us that the product is tracked from the field using the last three digits of the SKU number. In this case the SKU number was 198, which had been written on both the invoice from Costa and Sons and the purchase order from Mann to Spokane Produce. This number matches the SKU on Mann's Load Sheet, which confirms Romaine SS-2 Doz W/Liner (Romaine Sunny Shore 2 dozen with liner – Attachment 21).

Costa and Sons Farms

Farm Investigation

The farming business is divided among three different companies, Costa Farms Inc., Costa Family Farms, and Costa and Sons Farms. Costa and Sons Farms was the grower for the identified field in this traceback investigation. Mr. Mike Costa, Harvesting Manager, Costa and Sons Farms met FDB Investigator Carol Myers and FDA Investigators Bill Weiss and Erica Pomeroy on August 8, 2002 at the identified field, Abrams 14B (lot number 367) in Chular, California (Attachment 22). Abrams 14B appeared to be a well-maintained field, surrounded by other farm acreage with no visible animal activity. The identified field was planted in celery at the time of the inspection. The only farm activity observed was watering by overhead sprinklers (Attachment 23). No operating farm equipment, portable restrooms, or farm workers were observed on or near Abrams 14B at the time of the inspection.

Costa and Sons Farms rents Abram 14B from Abe Abrams, Salinas, California. The water source for this field is supplied by two wells. The west well (located on the northwest corner of Abrams 15) supplies approximately 80% of the water to Abrams 14B and the east well (located on the southeast corner of Abrams 11) supplies the other 20% of water. FDA investigators took well water samples from both wells (Attachment 24). The FDA laboratory analysis determined that these samples were negative for *E. coli* 0157:H7. Costa and Sons Farms had the well water tested on August 6, 2002 by an independent laboratory. The results of these tests were negative for E. coli (Attachment 25).

The east well was housed in a small wooden structure with an earthen floor. The "floor" was muddy, but with little pooling of water. The west well was not enclosed in a structure (Attachment 23). Both wellheads appeared to have intact concrete seals.

Costa and Sons Farms denied use of any uncomposted manure in their farming operations. Green compost was last applied to Abrams 14B in the fall of 2000. The compost comes from Jim Clifton, Greenfield, California and is made from discarded mushroom soil and grape pomace (byproducts from wine making). The mushroom soil is purchased from Monterey Mushroom and contains heat-treated chicken manure from Foster Farms. Foster Farms provided documentation from California Food and Agriculture for a permit to process animal waste for feed (Attachment 26). This documentation describes the process the chicken manure goes through to become

feed. Synthetic fertilizers are applied via the drip system prior to planting. Other synthetic nutrients are applied through the drip system during the growing cycle as needed.

The traceback-identified romaine was planted May 1, 2002 on Abrams 14B and thinned approximately 28 days after planting. Southern Monterey County Labor Supply Inc. supplied the thinning and hoeing crews. Abrams 14B was harvested on July 5, 2002. Mid-Valley Harvest, Gonzales, California and E. H. Packing LLC, Yuma, Arizona supplied the harvest workers for the implicated romaine lettuce (Attachment 27). After harvest, Costa and Sons Farms transported the liner-boxed romaine to Mann Packing on open truck beds.

Mr. Costa said that the harvesting knives are usually cleaned once a week, either by dipping in a chlorine solution or plain water. Mr. Costa did not know the concentration of the chlorine solution. The equipment used for farming the fields are cleaned once a week by brushing with soap and water.

Mr. Costa said that Costa and Sons Farms inspect the toilets supplied by the contractors. Documents are not kept for toilet maintenance.

Environmental Investigation of River Ranch Fresh Foods, LLC

On July 20, 2002 FDB Investigator Carol Myers and FDA Safety Officer Julian Jung met with Mr. David P. Robinson, Vice President of Processing and Logistics for River Ranch and Ms. Anne Pauly, Quality Assurance Manager for River Ranch. The firm had heard of the E. coli outbreak in Washington and its link to Salinas grown romaine. Ms. Pauly said she anticipated a visit from FDB and had already prepared farm, processing plant, and traceforward information. River Ranch supplied documentation for all 6-ounce baggy chopped romaine (River Ranch product code is 955) shipped to the Albertson's Portland Distribution Center for the time periods between June 27, 2002 through July 9, 2002 (Attachment 28). These documents trace shipped product from the field to the Albertson's Distribution Center in Portland and also include the farm and processing quality assurance (QA) documents. Attachment 29 shows the movement of these shipments from River Ranch to Albertson's Portland Distribution Center.

The six ounce bagged romaine salad is packaged in clear plastic bags. The only printing on the individual bags is the River Ranch code. The River Ranch code stamped on each bag identifies the production line, date, shift, and the processing location. This number can be used to trace the product back to the farm and retrieve salad-processing information. Eighteen six-ounce bags of chopped romaine (18 X 6) are packaged in a cardboard box with a bar code tag affixed to the outside. This bar code tag can be used to access information from the farm through the processing procedures and is color-coded to identify the day received in cold storage. The pallet of boxed product is wrapped with shrink-wrap and another bar code tag is placed on the outside of the wrap.

The River Ranch processing plant is 56,000 square feet with 15 production lines. Environmental swabs are collected once a week and tested by Primus Laboratory for Listeria. Ms. Pauly stated that the firm has never had a positive for *Listeria*. The production lines are swabbed daily and tested for *E. coli*, total plate count (TPC), and total coliform by the firm's laboratory. Approximately ten random products are sampled a month for generic *E. coli*. Random product samples are collect each week and tested for *Salmonella* and *Shigella*. According to Ms. Pauly, River Ranch has never had positive tests for *Salmonella*, *Shigella*, or *E. coli*.

Ms. Pauly accompanied Investigator Myers and Safety Officer Jung on a walk-through of the processing plant. The plant was processing at the time of the walk-through. Foot dips were noted at entrances and hand sanitizers were observed near all processing lines. All employees working on the processing lines wore hairnets, smocks, and gloves. A water sample was taken from the "V-line" (the same line used for chopped romaine) by Investigator Myers and was tested to have an ORP of 785mV by an Oaktron ORP Testr Double Junction meter. Water samples are collected from the processing lines hourly and both total and free chlorine are measured and recorded (Attachment 28). The firm has set acceptable levels for total chlorine at 50-150ppm with a target level of 100ppm. The firm's acceptable levels for free chlorine are 2-7ppm with a target of 4ppm. Chlorine is added to the flume water via an automated pump and is tested at the end of the flume before product enters the shaker.

Once ready for shipment, processed salads are placed in cold storage with a First In-First Out policy. Product is color coded by day to identify the first day it was placed in cold storage. Chopped romaine is processed within 24 hours after harvest and shipped within 48 hours from processing. This product has a 17-day shelf life once it is bagged. Any pre-cut product that has been in cold storage for four days is pulled and given to local charities.

River Ranch

Farm Investigation

River Ranch contracts with growers to grow their products. Custom growing allows River Ranch to control the cultivation of their crops. Anne Pauly identified four ranches (five fields) as the sources for the chopped romaine salads shipped to Albertson's Portland Distribution Center during the time period of interest (Attachment 29). These ranches are Doud Ranch, Jacob Ranch, Chinn Ranch, and Anthony (Frew) Ranch. Contract farmers grew and cared for the romaine until it was ready for harvest. River Ranch took charge of the crop at harvest time, using their crews and equipment for harvesting.

River Ranch used their harvesting crews (25-26 people) to cut and core the romaine in the field. River Ranch implements a food safety harvesting program (Attachment 30). All field workers in contact with product wear hairnets, plastic sleeve covers, gloves, and plastic aprons. A field worker cuts the romaine from the stem and places it on a tray on the harvest table. Another worker uses a stainless steel knife with a plastic handle to trim the romaine. This is done on a food grade cutting board set in a stainless steel frame. Once trimmed, the core is removed using a stainless steel coring implement. The romaine is then placed on a food grade belt and transferred to lined plastic bins sitting on a truck. The romaine passes through a 100 ppm chlorine spray before entering the bin. City water is hauled to the field where it is mixed with 12.5% liquid sodium hypochlorite to make a chlorine solution of 100 ppm used in the belt spray. The concentration of this mixture is confirmed with test strips and the QA person records the results. Attachment 31 shows pictures of romaine lettuce harvesting.

All equipment is cleaned and sanitized at the end of the day. The belt, cutting boards, and stainless steel supports are first washed and scrubbed with soap and water and then rinsed with 200 ppm chlorine solution. Knives are left in a 200ppm quaternary ammonia solution when not in use. . The QA person, using test strips measures and records the concentration of the chlorine spray and quaternary ammonia every hour. When workers use the portable toilets, they must leave their gloves in a designated area and then wash their hands and dip their gloves in the same bucket of quaternary ammonia used for the knives, before returning to their workstations.

A QA person is assigned for each harvest crew. This person is responsible to make sure River Ranch's food safety harvesting program is being implemented by the harvest crew

On July 21, 2002 Investigator Myers and Rafael Rodriquez, Special Project Manager for River Ranch observed the harvesting of a River Ranch romaine crop. All harvest crew workers coming in contact with the product were observed wearing hairnets, sleeve covers, gloves, and aprons. The QA person in the presence of the FDB investigator tested the belt spray water with a chlorine test strip and found a level of 150ppm of total chlorine. The portable toilet was equipped with soap, water, and single use towels. A bucket containing a solution of quaternary ammonia was observed for the dipping of gloves and knives.

Jacob Ranch

On July 20, 2002 FDB investigator Carol Myers and Brian Snow, Grower Relations for River Ranch met John Massa, owner of Comgro Inc. at Jacob Ranch field 7C. Jacob Ranch is adjacent to the Auto Mall on Auto Center Circle in Salinas, California (Attachment 32). Ms. Pauly identified this field as supplying romaine for the River Ranch order number 847111 shipped to the Albertson's Portland Distribution Center July 9, 2002. Comgrow leases the field and custom farms Jacob Ranch for River Ranch. Field 7C is 5.3 acres. Mr. Massa said that his company does soil analysis, prepares the soil, plants the romaine, and hires crews to hoe and thin the romaine. Blas Packing, Salinas, California supplied the hoeing and thinning crews.

Mr. Massa said his company hasn't applied manure to field 7C since July 1999. Comgro adds synthetic fertilizers via the sprinkler lines. Lime or gypsum is also used as soil amendments. Comgro has not used any manure or compost containing manure on this field since they began leasing the property in July 1999. At the time of the field inspection there were no workers or equipment in the field. On July 20, 2002 the field was planted with romaine that was approximately two weeks past germination.

Overhead sprinklers water romaine planted on the Jacob Ranch until harvest date. Well water is used to water field 7C. Water is pumped from a well to an earthen reservoir and then pressurized and pumped via a closed pipe to field 7C. The well and reservoir are located approximately 2 miles from field 7C. Comgro has the well tested once a year for total coliform, *E. coli*, and fecal coliform (Attachment 33).

The romaine crop related to this investigation germinated May 1, 2002 and was harvested July 6, 2002.

Chinn Ranch

Ms. Pauly identified Chinn Ranch field 12 as the supplier of the processed romaine for River Ranch order numbers 845466, 845679, and 845680 shipped to the Albertson's Portland Distribution Center 6/ 26/02, 6/26/02, and 7/01/02 respectively. Mr. Massa, Mr. Snow, and Investigator Myers met at Chinn Ranch the evening of July 20, 2002. Chinn Ranch lot 12 is 7.6 acres and located off Sonjon Road in Salinas, California (Attachment 34). Comgro was responsible for planting and maintaining the romaine crop until the harvest date of June 26, 2002. Comgro Inc. is a farming company that leases land and custom grows for their customers. River Ranch was responsible for the harvest.

Comgro used grape pomace compost, Lot 160, as a soil amendment for this field. A compost lot is made up of ingredients that are mixed and aerated in the same windrow. Three tons per acre of grape compost (Lot 160) was applied March 2002 to Chinn Ranch 12. The compost is made by composting grape pomace (supplied by local wineries) in windrows while monitoring time and temperature. Comgro reported that they follow the California Code of Regulations, Title 14 for their composting process. Cow manure from the San Joaquin, California area and/or chicken manure from Central Coast Fryers, Gustine, California is sometimes mixed with grape pomace before composting. Comgro reportedly does not mix grape compost with manure for all their fields. The nutrient composition of the field determines which type of compost is applied to the fields. The last application of compost-containing manure to Chinn field 12 was in July 1999. Compost Lot 160 reportedly did not contain any animal manure. The compost used in Lot 160 was analyzed by Primus Laboratory and was found to be negative for *E. coli, Listeria, E. coli* 0157:H7, and *Salmonella* (Attachment 35). Lot 160 was also analyzed for heavy metals (Attachment 36).

Chinn Ranch field 12 was watered with tertiary treated water from Monterey County Recycling Project. A private laboratory analyzes water samples for *E. coli*, coliform, and nutrients once a year (Attachment 33). Comgro also has the Chinn Ranch 12 water analyzed once a year (Attachment 37). Fertilizers are either shanked (tilled) into the soil or applied through the sprinkler system.

Chinn field 12 is in a valley below sea level. Flooding is not uncommon on this field during heavy rains. Pumps are used to remove rainwater when necessary. A county drainage ditch for floodwater borders the north side of Chinn field 12.

At the time of the field visit, broccoli was planted on field 12 (Attachment 38). The identified romaine supplied to River Ranch germinated on April 15, 2002 and was harvested on June 26, 2002.

Chinn Ranch field 3 supplied product for River Ranch order numbers 847032 and 846740 (Attachment 28 and 29). This ranch was not visited due to time constraints. Mr. Massa said that field 3 is supplied with well water and is farmed similarly as Chinn field 12. Chinn field 3 had green waste and cow manure compost applied in September, 2001. All other organic soil amendments applied to field 3 since 1997 have been free of manure according to George Fontes, Co-Owner of Comgro.

Doud Ranch

On August 21, 2002, Investigator Carol Myers accompanied by Brian Snow met Bob Martin, General Manager for Rio Ranch and Ed Morales, Food Safety Manager for Growers Express at Doud Ranch. Doud Ranch is located south of King City adjacent to Lonoak Road approximately two miles east off of the 1st Street Exit from Highway 101 (Attachment 39). Rio Farms owns Doud Ranch and are partners of Growers Express. Doud Ranch supplied romaine for River Ranch order number 845680 shipped to Albertson's Portland Distribution Center July 1, 2002.

Mr. Martin identified fields 20A (5.0 acres), 20B (12.1 acres), and 20D (12.6 acres) as supplying romaine for River Ranch order number 845680. Other cultivated fields surrounded these fields. Rio Farms custom farms for River Ranch. For these fields, River Ranch harvested the following acreage, 0.7 acres from 20A, 8 acres from 20B, and 8.2 acres from 20D. These fields were planted between April 1 and April 22, 2002. Rio Farms harvested the remainder of the acreage as commodity (romaine heads boxed in the field) at the same time as the River Ranch harvest.

Rio Farms hauls grape crush from San Miguel, California and places it in piles, letting it naturally breakdown into grape pomace. Rio Farms applies the grape pomace as a soil amendment. Rio Farms stopped using manure 18 years ago. A soil amendment, mushroom compost, is supplied by Jim Sorenson, Modesto, California, and is composted with onions, humic acid, and gypsum. The mushroom compost is purchased from Monterey Mushroom and contains Foster Farms' treated chicken manure. The chicken manure passes through a 90-foot rotary kiln dryer (starting temperature of 650 ° F). The manure also contains rice hulls. The "composted" manure takes about seven to ten minutes to pass through the dryer. Synthetic fertilizers are shanked into the soil or added through the sprinkler system prior to planting.

Two wells are used to water Doud Ranch. Both wells were inspected by Investigator Myers and found to have intact well casings with sealed wellheads. Water is pumped from the wells to a reservoir before entering the sprinkler system. The wells are tested once a year. The latest well water testing was on April 18, 2002 and was negative for *E. coli* (Attachment 40). The earthen reservoir was approximately 100 yards in width. Tules (similar to cattails) were observed growing in the reservoir and birds were present. Water analysis is not done on the reservoir water.

Rio Farms use their own employees for all farm activities. Rio Farms trains their employees in Good Agriculture Practices and food safety at the beginning of the season. Each employee has a manual produced by Growers Express that they use during the training. Mr. Ed Morales, Food Safety Manager for Growers Express, gives the training. Mr. Morales verbally goes through the manual, explaining the document and employee expectations. Each employee signs a log to document his or her training. River Ranch harvest crews cut, cleaned, and cored their portion of romaine in the fields as previously described.

Frew Ranch (Anthony Ranch)

On August 21, 2002 Investigator Carol Myers and Brian Snow met Scott Anthony, owner of Anthony Farms and Peter Iverson, Ranch Manager for Harley Ranch. Anthony Farms leases and farms land in the Salinas Valley. Frew Ranch field H117 is managed by Harley Ranches in which Anthony Farms is part owner. Frew Ranch field H117 is located west off of Highway 101 on Central Avenue (Attachment 41). Frew Ranch field H117 supplied romaine lettuce for River Ranch order number 846740 as identified by Ms. Pauly (Attachment 28).

The romaine crop related to this investigation was planted in April 2002 and harvested at the end of June 2002. Frew Ranch has not had manure applied to field H117 for the past 40 years. Fertilizers are shanked into the soil or applied through the watering system. The crop was sprinkled until one month after germination and then drip irrigated until harvest. Harley Ranch was responsible for the crop until harvest at which time River Ranch took responsibility.

A well approximately 1.5 miles away on the eastside of Highway 101 supplies water for Frew Ranch. Mr. Iverson stated that the well is located in a pump house with a sealed wellhead on a cement casing. The well site was not visited due to time constraints. Water is pumped from the well to an earthen reservoir located on the northwest corner of field H117. The reservoir is approximately 50 yards across. Mr. Iverson stated that copper sulfate is added to the water when needed to discourage plant and algae growth. The Frew Ranch well and reservoirs are tested once a year for *E. coli*. The well and reservoir were last tested June 12, 2002 and both were negative for *E. coli.* (Attachment 42).

Summary

FDB received notification from FDA of 40 confirmed cases of *E. coli* 0157:H7 illnesses in Washington State during the time period of July 11-15, 2002. The outbreak occurred at a drill team/dance camp at EWU. Epidemiological investigation of these cases supported an association with romaine lettuce. Six other cases (4 cases in Washington, 1 case in Idaho, and 1 case in Minnesota) not associated with the EWU outbreak were identified by WDH. The two suppliers for the romaine consumed in Washington were Spokane Produce and Albertson's. FDA identified four California firms (Capurro Farms, Mann Packing, Ocean Mist, and River Ranch, LLC) as the most likely suppliers) of the implicated romaine lettuce. FDB Emergency Response Unit (ERU) staff and FDA Alameda staff began an investigation of the California suppliers on August 2, 2002. Ocean Mist was later determined not to be a likely supplier of the implicated romaine lettuce. The three suppliers identified 12 fields in the Salinas area where the lettuce was grown. ERU staff visited 11 of these fields with the ranch managers and obtained farming practices information.

Lettuce shipped to Spokane Produce for processing was shipped as heads in either lined or waxed boxes and was either vacuum cooled or hydrovacuum cooled in California. Lettuce shipped to Albertson's was processed as chopped romaine at River Ranch Fresh Foods in Salinas, California. FDB Investigator Carol Myers completed a walk-through of River Ranch Processing plant and observed satisfactory sanitation practices. The plant was routinely doing environmental sampling and swabbing and also monitoring and documenting flume water chlorination levels.

One farm applied green waste and cow manure compost on September 1, 2001. Two ranches (four fields) applied mushroom compost, containing chicken manure compost within the last year. Three farms (6 fields) applied grape pomace as a soil amendment. Further investigation of manure containing composts will be conducted by FDB.

Intervention

On July 29, 2002, FDA issued an Alert urging consumers to discard 5-pound bags of "Romaine Toss" distributed by Food Services of America (Attachment 43).

Recommendations

Coolers

- Current Unikool procedures for maintaining hydrovacuum water quality are inadequate to prevent cross contamination. Recirculated hydrovacuum water should be maintained in a sanitary condition.

Harvest

- Hand harvesting tools should be cleaned and sanitized frequently (at least daily).
- Hand harvesting knives used to cut heads of lettuce should be made of stainless steel and nonporous handles to allow for optimal sanitation.

Growers

- Growers should be aware that irrigation water (well, canal, tertiary treated, and reservoir waters) could potentially be a source of pathogens. According to the Good Agricultural Practices (GAPs), water quality should be adequate for its intended use. The GAPS state "the quality of water in direct contact with the edible portion of produce may need to be of better quality compared to uses where there is minimal contact." This statement refers to water used in field operations (irrigation, applications of pesticides and fertilizers), cooling and frost control.
- Growers should be very cautious in the use of compost containing animal manure. Small samples (a single 25-gram sample for 1 ton of finished compost) for microbial testing may give misleading results. According to the GAPs, growers should reduce the introduction of microbial hazards to produce from animal manure. The GAPs state, "Good agricultural practices for the use of animal manure or biosolids include treatments to reduce pathogens and maximizing the time between application to production areas and harvest of the crops."
- Growers should be aware that cross contamination could result when using the same equipment to transfer, haul, or turn various stages of material in the composting process.

Composters

- Composters should be aware that cross contamination could occur by foot traffic from one composting stage to another and when using the same equipment to transfer, haul, or turn various stages of material in the composting process. Appropriate precautions should be taken to minimize the chance of cross contamination.
- Composters should be aware that wind and water could spread pathogens and therefore should situate composting and manure sites as far as practicable from crops. Also, barriers or physical containment should be considered to reduce the chance of wind or water spread of pathogens.
- Methods for microbial testing of compost containing animal manure should be reviewed to optimize the chances of recovering pathogens.

Third Party Auditors/Private Laboratories

- Third party auditors should train their employees in proper sampling methods and prevention of cross contamination.
- Third party audit personnel should be aware that cross contamination could occur by foot traffic from one composting stage to another. Appropriate precautions should be taken to minimize the chance of cross contamination.
- Methods for microbial testing of manure containing compost should be reviewed to optimize the chances of recovering pathogens if present.

Attachments

1. Dance Camp *E. coli* O157:H7 Outbreak, July 2002 epidemiological data
2. Ocean Mist Farms Daily Cooling Work Sheet
3. Picture of hydrovacuum tubes
4. Pictures of cooling equipment and procedures A-D
5. Ocean Mist SOP's "Microbiological Control of Re-circulated Water Systems"
6. Ocean Mist Farms Water Treatment Log
7. Ocean Mist Farms ORP Monthly Calibration Report
8. Ocean Mist customer order records
9. Maps of Mortensen Ranch and Boggiattio Ranch
10. *E. coli* 0157:H7 Romaine Lettuce California Traceback Investigation Ocean Mist Cooling
11. FDA water analyses for Mortensen Ranch and Boggiatto Ranch
12. Monterey Regional Water Pollution Control Agency "Tertiary Recycled Water Data"
13. Valley Pride, Inc. Mix Lettuce Crews employee list
14. Capurro Marketing, LLC shipping invoices
15. *E. coli* 0157:H7- Romaine Lettuce California Traceback Flow Diagram
16. FDA water analyses for Balich Ranch, Hudson Ranch, and Struve Ranch
17. Unikol cooling documentation of Dobler and Sons romaine lettuce shipped to Spokane Produce
18. Unikool "Equipment Cleaning Checklist" for hydrovacuum operators
19. FDA report of analysis for water sample taken from hydrovacuum 105HV
20. Mann's Packing Company, INC. invoices for shipped lettuce to Spokane Produce
21. Mann's Packing Company, INC. "Field Pack Received Maintenance" records
22. Costa and Sons Farm Directions and Diagram
23. Pictures of Costa and Sons Farms
24. FDA water analyses of Abrams 14B wells
25. Costa and Sons Farms independent laboratory well water analysis
26. Foster Farms "CDFA Application For Permit To Process Animal Waste For Feed"
27. E.H. Packing LLC invoice for Costa and Sons Farms
28. River Ranch shipping and quality control documentation for identified shipments to Albertson's
29. *E. coli* – Romaine Lettuce River Ranch Fresh Foods, LLC Traceforward Investigation
30. River Ranch's food safety practices
31. Pictures of River Ranch romaine lettuce harvesting crew
32. Jacob Ranch map
33. Well water analysis for Jacob Ranch well
34. Map for Chinn Ranch fields
35. Primus laboratory analysis for Comgro grape pomace lot 160
36. Heavy metal analysis for Comgro grape pomace lot 160
37. Well water analysis for Chinn Ranch 12
38. Picture of Chinn Ranch 12
39. Map for Doud Ranch fields
40. Well water analysis for Doud Ranch wells
41. Map for Frew Ranch
42. Well water analysis for Frew Ranch well
43. FDA Press Release July 29, 2002